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10/587,837	04/10/2007	Heike Barlag	32860-001100/US	9815

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EXAMINER	
DIETERLE, JENNIFER M	

ART UNIT	PAPER NUMBER
1759	

NOTIFICATION DATE	DELIVERY MODE
02/16/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/587,837	BARLAG ET AL.	
	Examiner	Art Unit	
	Jennifer Dieterle	1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *11-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-28 are pending.

Claims 11-20 have been withdrawn **without** traverse in the reply filed on 8/18/10.

Claims 1-10 and 21-28 are being examined.

Comments

1. The objection to figure 9 has been withdrawn due to applicant's filing of corrected drawing sheets and amendments to their specification filed 12/15/10.

2. The rejection of claim 1 and claims 2-10, 21-25 and 28, which depend from claim 1, under 35 U.S.C. 112, first paragraph is maintained.

3. The rejection of claim 1 and claims 2-10, 21-25 and 28, which depend from claim 1, under 35 U.S.C. 112, second paragraph, regarding the ambiguous claim language has been withdrawn due to applicant's amendment thereof.

4. The rejection of claim 3 under 35 U.S.C. 112, second paragraph is maintained. Claim 3 recites the limitation "when measuring oxidation currents" in line 2; however, there is no mention of *measuring oxidation currents* in claim 1. There is insufficient antecedent basis for these limitations in the claim.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph is maintained. Claim 4 recites the limitation "measuring reduction currents" in line 2; however,

there is no mention of *measuring reduction currents* in claim 1. There is insufficient antecedent basis for these limitations in the claim.

6. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to vague language has been withdrawn due to applicant's amendment thereof.

7. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to vague language has been withdrawn due to applicant's amendment thereof.

Response to Arguments

8. Applicant's arguments filed 12/15/10 have been fully considered but they are not persuasive.

9. Beginning with applicant's remarks concerning the rejection of claims 1 and claims 2-10, 21-25 and 28, which depend from claim 1, under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement, applicants remarks that there are various examples in the disclosure on how pulse length can be chosen, for example see figures and claims (applicant's arguments page 13). Applicant also remarks that one skilled in the art knows how to choose the values (applicant's arguments page 14). These are not persuasive for the following reasons. First, applicant refers to figure 3 as a basis for selecting pulse lengths. It is noted that figure 3 represents the current

density as a function of the pAP concentration for various pulse trains. Figure 3 contains multiple *pulse trains* (i.e. 31-34). Additionally, figure 3 actually has a set measuring phase that amounts to 0.25 sec and a set relaxation phase 0.75 sec. The current measurement takes place 0.24 sec after the start of the measuring phase (see applicant's PG Pub section 0054). Therefore, with regard to figure 3, there is no clear direction as to which *pulse train,* numerals 31-34 is preferred or as to how one skilled in the art would select an appropriate pulse length to arrive at a desired pulse train. Additionally, figure 3 has "set" the pulse lengths at times .25 and .75 seconds and has not provided clear criteria as to how these variables were arrived at which is the crux of claim 1. Therefore, applicant's remarks that figure 3 show applicant's claimed invention and would enable one skilled in the art to practice applicant's claimed invention, are not persuasive and it is maintained that there is no clear criterion is noted in figure 3 to enable one skilled in the art to make a choice as to the appropriate pulse length or time. It is also noted that applicant has stated that one skilled in the art would, from figure 3, be able to select pulse lengths. If this is the case, examples (i.e. patent or nonpatent literature) will need to be provided to provide evidence how one skilled in the art would utilize figure 3 to select pulse lengths.

Second, applicant notes that figures 5 and 6 adequately describe the appropriate relaxation phase duration and that it is within the ability of one skilled in the art to perform the method. As stated in the previous enablement rejection mailed 9/17/10, with regard to figures 5 and 6, numerals 51-54 and 61-64 are the results of different relaxation phase durations. There is no indication of which one is preferred or as to

how one skilled in the art would select an appropriate relaxation phase duration. No clear criterion is noted in the specification to enable one skilled in the art to make a choice as to the appropriate pulse length or time. Applicant's response that one skilled in the art would know is not sufficient to overcome the enablement rejection without specific examples showing how one skilled in the art would deduce from figures 5 and 6 how to select which relax time over another to arrive at a method of selecting a pulse length. Arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Third, it is noted that applicant remarks that at 1/10 Hz may provide much less measurement fault and that one skilled in the art can choose the pulse lengths, with the given values and relations in figures 5 and 6 the pulse lengths (applicant's remarks page 15). It is noted that figure 5 is a depiction of the dependence of the current density upon time. Lines 51 to 54 in figure 5 are different relaxation-phase durations between 0.255 and 4.755 seconds, but would appear that the potential is high (PG Pub section 0063-66). Lines 61-64 in figure 6 also appear to be different relaxation-phase durations, but at a set potential of -300mV which improves signal constancy. However, setting a potential does not enable one skilled in the art to select an appropriate pulse length. While according to applicant's specification 1 Hz and a relaxation potential of -300 mV create a signal drop and a drop in error of approximately 1% of the expected measured value, this would be useful if one were to select the frequency and potential, not the pulse length. As shown in figure 6, the time goes from 1-10 seconds and there are four

points along this timeline. Additionally, this provides no insight into the selection of the measuring phase pulse.

10. Applicant's remarks concerning Gunasingham et al. are also not persuasive. Applicant notes that "currents from the oxidation or reduction of TTF are added to the measuring signal as error". Therefore, TTF must be measured and since the entire system of Gunasingham is subjected to pulsed detection (i.e. a measuring and relaxation phase, see figure 1).

11. It does not appear that applicant has provided any remarks concerning the device claims 26 and 27 (see applicant's remarks page 19). However, it is maintained that both Bindra et al. and Henkens et al. anticipate the device. As noted in the previous office action dated 9/17/10, Bindra et al. teach a biosensor comprising a means, i.e. PARC Model 400, for pulsing the potential of the working electrode between measuring and relaxation phases (see col. 1 on page 2567 under Apparatus and Nafion Coating headings). If the PARC is designed to apply a repeating sequence of three applied potentials (i.e. measure, oxidize, and reactivate) according to a specified timing, this would read on the means for selecting measuring phase pulse length and relaxation pulse length as the device is programmable. Finally, Bindra et al. teach the use of a Princeton Applied Research Model 400 electrochemical detector and a Shimadzu CR 4A integrator which is used to process the detector output. Additionally, Henkens et al. teach pulsed electrochemical detection in which there is a means for applying a series

of pulses which itself can be programmed by a user as to what pulse lengths, times, and strengths (i.e. means for selecting and multiplexed potentiostat) and a detection/measuring means (i.e. electrochemical pulse analyzer)(col. 5, lines 1-20; col. 6, lines 15-35).

Applicant is reminded that device claims are examined based on structure and not function. It is noted that claims 26 and 27 contain numerous references of *intended use*. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458,459 (CCPA 1963). In the present case, both Henkens et al. and Bindra et al. teach a device comprising a means to apply a pulse (i.e. PARC Model 400 or multiplexed potentiostat) and detect/measure a reaction (i.e. Princeton Applied Research Model 400 or electrochemical pulse analyzer) which are capable of performing the intended use stated in claims 26 and 27.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 1 and claims 2-10, 21-25 and 28, which depend from claim 1, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement

requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1989) otherwise undue experimentation would be involved in determining how to practice and use applicant's invention. Although the statute itself does not use the phrase "undue experimentation", it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation as stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and in *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Specifically, in *In re Wands* the Court set forth a non-exhaustive list of factors to be considered in determining whether undue experimentation would be involved in making and/or using the claimed invention. These factors include, but are not limited to:

- the breadth of the claims;
    - In the instant case, the claims refer to a method of selecting pulse lengths.
- the nature of the invention and state of the prior art;
    - In the instant case, the nature of the invention, i.e. pulse voltammetry/detection is well known in the art as shown in

Lewandowski et al. (US 4,897,162, see entire document) and Henkens et al. (US 6,391,558 B1, see col. 37-38).

- the level of one of ordinary skill and the level of predictability in the art;
    - Selecting pulse lengths is known as shown in Bindra et al. (Anal. Chem. 1989, 61 2566-2570, see col. 1 on page 256).
- the amount of direction provided by the inventor and the quantity of experimentation needed to make or use the invention based on the content of the disclosure; and
    - In the instance case, the amount of direction provided by the inventor does not provide one skilled in the art the ability to arrive at a specific pulse length or provide one skilled in the art with a method by which a pulse length is selected. In the instant case, it is not clear from the specification how pulse lengths are chosen which is what is being claimed. In section [0056] of applicant's PG Pub Document it appears that applicant has "set" the pulse lengths at times .25 and .75 seconds and has not provided clear criteria as to how these variables were arrived at which is the crux of claim 1. Additionally, with regard to figures 5 and 6, applicant notes that a measurement is being taken over a 10 second time period; however, it is not clear what these time periods represent. Are they the time of the measurement/relaxation phase? In the specification at section 00664 it refers to the time period as the first

10 seconds of measurement, but also notes other times such as .25 and 4.75 seconds.

- In addition, section 0074 notes that the pulse length, the repetition rate and the level of the potential can be predetermined which would not lead one to a method of selecting a pulse length if it is already determined.
- Additionally, with regard to figures 5 and 6, numerals 51-54 and 61-64 are the results of different relaxation phase durations. There is no indication of which one is preferred or as to how one skilled in the art would select an appropriate relaxation phase duration. No clear criterion is noted in the specification to enable one skilled in the art to make a choice as to the appropriate pulse length or time.

- the existence of working examples;
  - Applicant provides graphs (figures 5 and 6) as noted above, but does not detail/explain which relax time (numerals 51-54, 61-64) is better or how to select which relax time over another to arrive at a method of selecting a pulse length.
  - It does not appear that there are any working examples that specifically explain how one is to arrive at or the criteria required to select a pulse length.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 3 is rejected under 35 U.S.C. 112, second paragraph. Claim 3 recites the limitation "when measuring oxidation currents" in line 2; however, there is no mention of *measuring oxidation currents* in claim 1. There is insufficient antecedent basis for these limitations in the claim.

14. Claim 4 is rejected under 35 U.S.C. 112, second paragraph. Claim 4 recites the limitation "measuring reduction currents" in line 2; however, there is no mention of *measuring reduction currents* in claim 1. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-4 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunasingham et al. (J. Electroanal. Chem. 287, 1990, 349-362).

Regarding claims 1, 2 and 28, Gunasingham et al. teach a method for pulsed amperometric detection of the concentration of a mediator (TTF) in a biological system

(page 350) in which the potential on the working electrode is pulsed by a potentiostat (page 351) such that the measurement and relaxation phases alternate (see figure 1, page 351). The phases being selected such that the duration of the measurement phase (PD) is chosen such that, towards the end of the pulse, the capacitive current is small in comparison to the Faraday current (page 353, "Effect of pulse duration"). A relaxation phase as shown in figure 1 so that the concentration gradient is relaxed is seen in figure 4. Thus the excess positively charged TTF that is not consumed will be reduced back to neutral TTF at the electrode surface and be available by the next oxidation pulse (page 354 "Effect of clock time").

Regarding claims 3 and 4, Gunashingham et al. teach measuring oxidation currents (see figure 3) and has a reduction potential wherein the excess charged TTF that is not consumed will be reduced back to the neutral TTF at the electrode surface so that it will be available by the next oxidation pulse (page 354, pulsed redox cycling).

16. Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bindra et al. (Anal. Chem. 1989, 61 2566-2570, see col. 1 on page 256).

Regarding claims 26 and 27, Bindra et al. teach a biosensor comprising a means, i.e. PARC Model 400, for pulsing the potential of the working electrode between measuring and relaxation phases (see col. 1 on page 2567 under Apparatus and Nafion Coating headings). If the PARC is designed to apply a repeating sequence of three

applied potentials (i.e. measure, oxidize, and reactivate) according to a specified timing, this would read on the means for selecting measuring phase pulse length and relaxation pulse length as the device is programmable. Finally, Bindra et al. teach the use of a Princeton Applied Research Model 400 electrochemical detector and a Shimadzu CR 4A integrator which is used to process the detector output.

17. Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Henkens et al. (US 6,391,558 B1).

Regarding claims 26 and 27, Henkens et al. teach pulsed electrochemical detection in which there is a means for applying a series of pulses which itself can be programmed by a user as to what pulse lengths, times, and strengths (i.e. means for selecting and multiplexed potentiostat) and a detection/measuring means (i.e. electrochemical pulse analyzer)(col. 5, lines 1-20; col. 6, lines 15-35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 5, 10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunasingham et al. (J. Electroanal. Chem. 287, 1990, 349-362), as applied above to claims 1 and 3, in view of Bindra et al. (Anal. Chem. 1989, 61 2566-2570).

Regarding claim 5, 10 and 21, Gunasingham et al. teach a method for selecting pulse lengths, but does not specifically teach the claimed repetition rate or phase times.

Bindra et al. teach pulsed amperometric detection and that it is known in the art to utilize current-potential response curves for the analyte of interest in order to select the appropriate pulse lengths and repetition rates (page 2567, col. 1, "Nafion Coating")

It is noted that applicant has provided numerous dependent claims related to the phase lengths. Additionally, applicant's specification at section 0074 notes that the pulse length, the repetition rate and the level of the potential can be predetermined. In particular, the pulse lengths of the measuring phases and the relaxation phases can be set separately and be of different lengths. The potentials can also be of different magnitudes.

Since no specific guidance or criticality is provided as to the phase lengths or repetition rates are noted, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II). Therefore, it would have been obvious to a person of ordinary skill in the art to select the appropriate repetition rates and phase lengths to facilitate effective concentration detection using pulsed amperometric detection.

Additionally, it would have been obvious to one skilled in the art to utilize a predetermined current-potential response curve to select a repetition rate and phase length in Gunasingham et al. appropriate for the desired detection as taught by Bindra et al. because these curves are known and utilized in the art.

19. Claims 6-8 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gunasingham et al. (J. Electroanal. Chem. 287, 1990, 349-362), as applied above to claims 1, 3, and 4, in view of Buck et al. (WO 01/21827).

Regarding claims 6-8 and 22-24, Gunasingham et al. teach a method for selecting pulse lengths which can be rectangular (see figure 1), but does not specifically teach the claimed relaxation and measuring phases.

Buck et al. teach a method of utilizing pulsed amperometric detection. Specifically, figures 6-9 show that different pulse lengths can be selected. Figure 6, shows a pulse sequence in which two pulses of oxidative potential of different duration are applied to the sensor, interspersed with recovery intervals with reducing potential. By comparing the current profile from the first pulse with that from the second, information on the rate of enzymatic turnover of the substrate, and the rate of electron diffusion within the sensor may be obtained. Between the oxidative potential applications, the reducing potential ensures that all of the mediator is returned to its initial state prior to the application of the next oxidizing potential. Figure 7 shows a sequence in which the duration of the intervals between the pulses is changed. By comparing the current observed from the second pulse to that from the first, information on the recovery time of the sensor can be gained. The recovery time yields information not only on analyte concentration, but also on diffusion into the hydrophilic matrix. Measuring the rest potential of the sensor between the potentiostatic pulses also provides information on the sensor recovery. Figures 8 and 9 demonstrate measurement protocols, which combine changes in the pulse interval with changes in

the pulse width. The controller can select from a variety of sequences and durations of amperometric measurement intervals and recovery intervals to determine not only the analyte concentration, but also probe the condition of the sensor for enzyme activity, diffusion of substrate and mediator within the sensor, and diffusion of substrate into the sensor (see pages 13-14). In summary, Buck et al. teach that one skilled in the art would select the appropriate pulse length or curve profile in order to obtain the desired information be it recovery time, condition of the sensor, enzyme activity, or rate of reaction.

It is noted that applicant has provided numerous dependent claims related to the variation in pulse length and shape. Additionally, applicant's specification at section 0074 notes that the pulse length, the repetition rate and the level of the potential can be predetermined. In particular, the pulse lengths of the measuring phases and the relaxation phases can be set separately and be of different lengths. The potentials can also be of different magnitudes.

Since no specific guidance or criticality is provided as to the curve type or phase durations and no unexpected results are noted, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the

ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II). Therefore, it would have been obvious to a person of ordinary skill in the art to select the appropriate pulse course and phase length to facilitate effective concentration detection using pulsed amperometric detection.

Additionally, it would have been obvious to one skilled in the art to select a pulse length and curve in Gunasingham et al. appropriate for the desired detection as taught by Buck et al. because selecting these parameters will lead to the desired detection be it recovery time, condition of the sensor, enzyme activity, or rate of reaction.

20. Claims 9 and 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gunasingham et al. (J. Electroanal. Chem. 287, 1990, 349-362) and Buck et al. (WO 01/21827), as applied above to claim 8, in view of Bindra et al. (Anal. Chem. 1989, 61 2566-2570).

Regarding claims 9 and 25, Gunasingham et al. teach a method for selecting pulse lengths, but does not specifically teach the claimed repetition rate or phase times.

Bindra et al. teach pulsed amperometric detection and that it is known in the art to utilize current-potential response curves for the analyte of interest in order to select the appropriate pulse lengths and repetition rates (page 2567, col. 1, "Nafion Coating")

It is noted that applicant has provided numerous dependent claims related to the phase lengths. Additionally, applicant's specification at section 0074 notes that the pulse length, the repetition rate and the level of the potential can be predetermined. In

particular, the pulse lengths of the measuring phases and the relaxation phases can be set separately and be of different lengths. The potentials can also be of different magnitudes.

Since no specific guidance or criticality is provided as to the phase lengths or repetition rates are noted, it is not inventive to discover the optimum or workable ranges by routine experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The discovery of an optimum value of a known result effective variable, without producing any new or unexpected result, is within the ambit of a person of ordinary skill in the art. See *In re Boesch*, 205 USPQ 215 (CCPA 1980)(see MPEP § 2144.05, II). Therefore, it would have been obvious to a person of ordinary skill in the art to select the appropriate repetition rates and phase lengths to facilitate effective concentration detection using pulsed amperometric detection.

Additionally, it would have been obvious to one skilled in the art to utilize a predetermined current-potential response curve to select a repetition rate and phase length in Gunasingham et al. appropriate for the desired detection as taught by Bindra et al. because these curves are known and utilized in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dieterle whose telephone number is (571) 270-7872. The examiner can normally be reached on Monday thru Thursday, 9am to 4pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571) 272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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